

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings of claims in the application.

Listing of Claims:

1. (Amended) A method of treating epidermolysis bullosa ~~a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin~~ comprising applying to the skin of patients in need thereof an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:
 - (a) allantoin;
 - (b) an emulsifier system including:
 - (i) an acidic wax; and
 - (ii) an anionic emulsifier that is substantially hydrophilic and is soluble in water; and
 - (c) an acid to adjust the pH of the composition to a value in the range of from about 3.0 to about 6.0₋₂wherein the allantoin is stable in the emulsion across the pH range from about 3.0 to about 6.0.
2. (Original) The method of claim 1 wherein the pH of the composition is from about 4.5 to about 5.8.
3. (Original) The method of claim 1 wherein the emulsifier is selected from the group consisting of ammonium lauryl sulfate, sodium laureth sulfate, sodium oleyl succinate, ammonium lauryl sulfosuccinate, sodium dodecylbenzenesulfonate, ammonium laureth sulfate, sodium N-lauryl sarcosinate, and sodium lauryl sulfate.
4. (Original) The method of claim 3 wherein the emulsifier is sodium lauryl sulfate.
5. (Original) The method of claim 1 wherein the acidic wax is selected from the group

consisting of beeswax, carnauba wax, candelilla wax, siliconyl beeswax, siliconyl carnauba wax, and a synthetic acidic wax.

6. (Original) The method of claim 5 wherein the acidic wax is beeswax.
7. (Cancelled).
8. (Cancelled)
9. (Original) The method of claim 1 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.
10. (Original) The method of claim 9 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.
11. (Original) The method of claim 1 wherein the composition further comprises at least one of: (a) an emollient component comprising at least one ingredient selected from the group consisting of lanolin oil, cetyl alcohol, stearyl alcohol, and cod liver oil; (b) at least one antioxidant selected from the group consisting of butylated hydroxytoluene and butylated hydroxyanisole; (c) at least one herbal extract selected from the group consisting of St. John's wort extract, witch hazel extract, chamomile extract, and arnica extract; (d) a preservative component comprising at least one preservative selected from the group consisting of methylparaben and propylparaben; (e) tetrasodium EDTA; and (f) a solvent component comprising at least one solvent selected from the group consisting of ethylene glycol, propylene glycol, butylene glycol, and glycerin.
12. (Original) The method of claim 2 wherein the composition comprises an oil-in-water emulsion comprising: (a) water; (b) sodium lauryl sulfate; (c) propylene glycol; (d) tetrasodium EDTA; (e) citric acid; (f) lanolin oil; (g) cetyl alcohol; (h) stearyl alcohol; (i) an acidic wax

selected from the group consisting of beeswax, carnauba wax, candelilla wax, siliconyl beeswax, siliconyl carnauba wax, and a synthetic acidic wax; (j) cod liver oil; (k) butylated hydroxytoluene; (i) St. John's wort extract; (m) witch hazel extract; (n) chamomile extract; (o) arnica extract; (p) methylparaben; (q) propylparaben; (r) allantoin; and (s) fragrance.

13. (Original) The method of claim 12 wherein the acidic wax is beeswax.

14. (Original) The method of claim 12 wherein the composition comprises: (a) from about 50% to about 90% of water; (b) from about 0.5% to about 2.5% of 30% sodium lauryl sulfate; (c) from about 2.0% to about 9.0% of propylene glycol; (d) from about 0.05% to about 0.5% of tetrasodium EDTA; (e) from about 0.05% to about 0.5% of citric acid; (f) from about 5% to about 15% of lanolin oil; (g) from about 3% to about 10% of cetyl alcohol; (h) from about 1% to about 5% of stearyl alcohol; (i) from about 0.5% to about 2.5% of an acidic wax selected from the group consisting of beeswax, carnauba wax, candelilla wax, siliconyl beeswax, siliconyl carnauba wax, and a synthetic acidic wax; (j) from about 1.0% to about 7.0% of cod liver oil; (k) from about 0.1% to about 1.0% of butylated hydroxytoluene; (l) from about 0.05% to about 0.5% of St. John's wort extract; (m) from about 0.05% to about 0.5% of witch hazel extract; (n) from about 0.05% to about 0.5% of chamomile extract; (o) from about 0.05% to about 0.5% of arnica extract; (p) from about 0.1% to about 0.5% of methylparaben; (q) from about 0.1% to about 0.5% of propylparaben; (r) from about 0.5% to about 10.0% of allantoin; and (s) from about 0.05% to about 0.5% of fragrance.

15. (Original) The method of claim 14 wherein the acidic wax is beeswax.

16. (Original) The method of claim 14 wherein the composition comprises: (a) from about 55% to about 75% of water; (b) from about 1.0% to about 2.5% of 30% sodium lauryl sulfate; (c) from about 3.0% to about 6.0% of propylene glycol; (d) from about 0.1% to about

0.3% of tetrasodium EDTA; (e) from about 0.08 to about 0.35% of citric acid; (f) from about 8.0% to about 12.0% of lanolin oil; (g) from about 3.5% to about 7.5% of cetyl alcohol; (h) from about 1.0% to about 3.0% of stearyl alcohol; (i) from about 1.0% to about 2.5% of an acidic wax selected from the group consisting of beeswax, carnauba wax, candelilla wax, siliconyl beeswax, siliconyl carnauba wax, and a synthetic acidic wax; (j) from about 1.0% to about 4.0% of cod liver oil; (k) from about 0.2% to about 0.8% of butylated hydroxytoluene; (l) from about 0.05% to about 0.15% of St. John's wort extract; (m) from about 0.05% to about 0.15% of witch hazel extract; (n) from about 0.05% to about 0.15% of chamomile extract; (o) from about 0.05% to about 0.15% of arnica extract; (p) from about 0.15% to about 0.40% of methylparaben; (q) from about 0.10% to about 0.30% of opylparaben; (r) from about 0.50% to about 2.0% of allantoin; and (s) from about 0.1% to about 0.3% of fragrance.

17. (Original) The method of claim 16 wherein the acidic wax is beeswax.

18. (Original) The method of claim 16 wherein the composition comprises: (a) about 68.68% of water; (b) about 1.9% of sodium lauryl sulfate; (c) about 5.3% of propylene glycol; (d) about 0.15% of tetrasodium EDTA; (e) about 0.12% of citric acid; (f) about 10.6% of lanolin oil; (g) about 4.2% of cetyl alcohol; (h) about 2.0% of stearyl alcohol; (i) about 1.90% of an acidic wax selected from the group consisting of beeswax, carnauba wax, candelilla wax, siliconyl beeswax, siliconyl carnauba wax, and a synthetic acidic wax; (j) about 2.0% of cod liver oil; (k) about 0.5% of butylated hydroxytoluene; (l) about 0.1% of St. John's wort extract; (m) about 0.1% of witch hazel extract; (n) about 0.1% of chamomile extract; (o) about 0.1% of arnica extract; (p) about 0.3% of methylparaben; (q) about 0.25% of propylparaben; (r) about 1.50% of allantoin; and (s) about 0.20% of fragrance.

19. (Original) The method of claim 18 wherein the acidic wax is beeswax.
20. (Original) The method of claim 16 wherein the composition comprises: (a) about 61.18% of water; (b) about 1.9% of sodium lauryl sulfate; (c) about 5.3% of propylene glycol; (d) about 0.15% of tetrasodium EDTA; (e) about 0.12% of citric acid; (f) about 10.6% of lanolin oil; (g) about 4.2% of cetyl alcohol; (h) about 2.0% of stearyl alcohol; (i) about 1.90% of an acidic wax selected from the group consisting of beeswax, carnauba wax, candelilla wax, siliconyl beeswax, siliconyl carnauba wax, and a synthetic acidic wax; (j) about 2.0% of cod liver oil; (k) about 0.5% of butylated hydroxytoluene; (l) about 0.1% of St. John's wort extract; (m) about 0.1% of witch hazel extract; (n) about 0.1% of chamomile extract; (o) about 0.1% of arnica extract; (p) about 0.3% of methylparaben; (q) about 0.25% of propylparaben; (r) about 9.00% of allantoin; and (s) about 0.20% of fragrance.
21. (Original) The method of claim 20 wherein the acidic wax is beeswax.
- 22-136. (Withdrawn)
137. A method of treating epidermolysis bullosa ~~a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin~~ comprising applying to the skin of patients in need thereof an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:
- (a) allantoin;
 - (b) a carbohydrate polymer; and
 - (c) an emulsifier system comprising:
 - (i) an acidic wax; and
 - (ii) an anionic emulsifier that is substantially hydrophilic and is soluble in water;

wherein the pH of the composition is between about 3.0 and about 6.0; and

wherein the allantoin is stable in the emulsion across the pH range from about 3.0 to about 6.0.

138. (Original) The method of claim 137 wherein the pH of the composition is between about 5.0 and about 6.0.

139. (Original) The method of claim 137 wherein the acidic wax is selected from the group consisting of beeswax, carnauba wax, candelilla wax, siliconyl beeswax, siliconyl carnauba wax, and a synthetic acidic wax.

140. (Original) The method of claim 139 wherein the acidic wax is beeswax.

141. (Original) The method of claim 137 wherein the carbohydrate polymer is selected from the group consisting of galactoarabinan, polygalactose, and polyarabinose.

142. (Original) The method of claim 141 wherein the carbohydrate polymer is galactoarabinan.

143. (Original) The method of claim 137 wherein the anionic emulsifier that is substantially hydrophilic and soluble in water is selected from the group consisting of ammonium lauryl sulfate, sodium laureth sulfate, sodium oleyl succinate, ammonium lauryl sulfosuccinate, sodium dodecylbenzenesulfonate, ammonium laureth sulfate, sodium N-lauryl sarcosinate, and sodium lauryl sulfate.

144. (Original) The method of claim 143 wherein the anionic emulsifier that is substantially hydrophilic and soluble in water is sodium lauryl sulfate.

145. (Original) The method of claim 137 wherein the composition further comprises citric acid.

146. (Cancelled)

147. (Cancelled)

148. (Original) The method of claim 137 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

149. (Original) The method of claim 148 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.

150. (Original) The method of claim 137 wherein the composition further comprises at least one of: (a) a solvent component comprising at least one solvent selected from the group consisting of propylene glycol, butylene glycol, and glycerin; (b) an emollient component comprising at least one emollient selected from the group consisting of lanolin oil, cetyl alcohol, stearyl alcohol, and cod liver oil; (c) butylated hydroxytoluene; (d) tetrasodium EDTA; and (e) a preservative component comprising at least one preservative selected from the group consisting of methylparaben and propylparaben.

151-158. (Withdrawn)

159. (Amended) A method of treating epidermolysis bullosa ~~a skin condition or disease characterized by ulceration, inflammation, or blistering of the skin~~ comprising applying to the skin of patients in need thereof an allantoin-containing composition in a therapeutically effective amount, the allantoin-containing composition comprising an oil-in-water emulsion comprising:

(a) allantoin in a concentration of at least about 2.5%; and

(b) an emulsifier system comprising:

(i) an acidic wax; and

(ii) an anionic emulsifier that is substantially hydrophilic and is soluble in water;

wherein the pH of the composition is between about 3.0 and about 6.0; and

wherein the allantoin is stable in the emulsion across the pH range from about 3.0 to about 6.0.

160. (Original) The method of claim 159 wherein the acidic wax is selected from the group consisting of beeswax, carnauba wax, candelilla wax, siliconyl beeswax, siliconyl carnauba wax, and a synthetic acidic wax.

161. (Original) The method of claim 160 wherein the acidic wax is beeswax.

162. (Original) The method of claim 159 wherein the anionic emulsifier that is substantially hydrophilic and soluble in water is selected from the group consisting of ammonium lauryl sulfate, sodium laureth sulfate, sodium oleyl succinate, ammonium lauryl sulfosuccinate, sodium dodecylbenzenesulfonate, ammonium laureth sulfate, sodium N-lauryl sarcosinate, and sodium lauryl sulfate.

163. (Original) The method of claim 162 wherein the anionic emulsifier that is substantially hydrophilic and soluble in water is sodium lauryl sulfate.

164. (Original) The method of claim 159 wherein the composition further comprises citric acid.

165. (Cancelled)

166. (Cancelled)

167. (Original) The method of claim 137 further comprising administering an additional therapeutic agent in a therapeutically effective quantity.

168. (Original) The method of claim 167 wherein the additional therapeutic agent is selected from the group consisting of steroids, nonsteroidal anti-inflammatory agents, leukotriene antagonists, and monoclonal antibodies.

169. (Original) The method of claim 159 wherein the composition further comprises at least one of: (a) a solvent component comprising at least one solvent selected from the group

consisting of propylene glycol, butylene glycol, and glycerin; (b) an emollient component comprising at least one emollient selected from the group consisting of lanolin oil, cetyl alcohol, and stearyl alcohol; (c) tetrasodium EDTA; and (d) a preservative component comprising at least one preservative selected from the group consisting of methylparaben and propylparaben.

170. (Original) The method of claim 159 wherein the composition comprises: (a) from about 50.0% to about 90.0% of water; (b) from about 2.0% to about 9.0% of propylene glycol; (c) from about 0.50% to about 5.0% of a 30% solution of sodium lauryl sulfate; (d) from about 0.05% to about 0.50% of tetrasodium EDTA; (e) from about 0.05% to about 0.50% of citric acid; (f) from about 5.0% to about 15.0% of lanolin oil; (g) from about 3.0% to about 10.0% of cetyl alcohol; (h) from about 1.0% to about 5.0% of stearyl alcohol; (i) from about 0.50% to about 5.0% of an acidic wax selected from the group consisting of beeswax, carnauba wax, candelilla wax, siliconyl beeswax, siliconyl carnauba wax, and a synthetic acidic wax; (j) from about 0.10% to about 0.50% of methylparaben; (k) from about 0.10% to about 0.50% of propylparaben; (l) from about 2.5% to about 10.0% of allantoin; and (m) from about 0.05% to about 0.50% of fragrance.

171. (Original) The method of claim 170 wherein the acidic wax is beeswax.

172. (Original) The method of claim 170 wherein the composition comprises: (a) about 58.98% of water; (b) about 5.70% of propylene glycol; (c) about 3.00% of a 30% solution of sodium lauryl sulfate; (d) about 0.15% of tetrasodium EDTA; (e) about 0.12% of citric acid; (g) about 10.60% of lanolin oil; (h) about 4.20% of cetyl alcohol; (i) about 2.00% of stearyl alcohol; (j) about 3.00% of an acidic wax selected from the group consisting of beeswax, carnauba wax, candelilla wax, siliconyl beeswax, siliconyl carnauba wax, and a synthetic acidic wax; (k) about 0.30% of methylparaben; (l) about 0.25% of propylparaben; (m) about 9.0% of allantoin; and (n)

about 0.20% of fragrance.

173. (Original) The method of claim 172 wherein the acidic wax is beeswax.

Please add claims 174-179:

174 (New) The composition of claim 1 wherein the allantoin is stable in the emulsion across the pH range from about 4.0 to about 6.0.

175 (New) The method of claim 1 wherein the pH of the composition is from about 4.0 to about 6.0.

176 (New) The composition of claim 137 wherein the allantoin is stable in the emulsion across the pH range from about 4.0 to about 6.0.

177 (New) The method of claim 137 wherein the pH of the composition is from about 4.0 to about 6.0.

178 (New) The composition of claim 159 wherein the allantoin is stable in the emulsion across the pH range from about 4.0 to about 6.0.

179 (New) The method of claim 159 wherein the pH of the composition is from about 4.0 to about 6.0.